

IN THE DRAWINGS

Attached hereto are replacement drawings for figures 1 and 2 of record.

REMARKS

Applicant has submitted herewith a new sequence listing for sequence SEQ ID NO:19 and 20 in conformity with the understanding reached with the Examiner in a telephone interview conducted on May 27, 2010 in which the Examiner agreed as set forth in the Interview Summary dated June 3, 2010, that the filing of a new sequence listing for SEQ ID NO:19 showing position 17 to be “¹⁷Gln” and not “Glu” would be sufficient to overcome the new matter rejection and objection thereto.

Applicant has also submitted replacement sheets for new Figures 1-2. Fig. 1 is labeled SEQ ID NO:1 and Fig. 2 is labeled SEQ ID NO:2. Applicant had amended the Brief Description of the Drawings in the specification with the submission dated September 22, 2005 to state that Figs. 1 and 2 represent SEQ ID NO's 1 and 2, respectfully. Applicant believes that the submission hereof of Substitute Drawings for Figs. 1 and 2 is in compliance with MPEP 2422.02.

In the present application, numeric identifier <223> of SEQ ID NO:19 clearly reads “amino Acid Sequence of SEQ ID NO:1” and numeric identifier <222> reads as follows: “(1)...(92). According to the Table provided in 37 CFR 1.823, numeric identifier <222> is to denote the location of SEQ ID within the sequence.

Further, MPEP 2422.03 clearly states that:

“It is generally acceptable to present a single, general sequence in

accordance with the sequence rules and to discuss and/or claim variants of that general sequence without presenting each variant as a separate sequence in the Sequence Listing”.

It should be understood, as applicants have repeatedly asserted, that SEQ ID 19 is a specific portion of SEQ ID 1. Consequently, the clear statement following numeric identifiers <222> and <223> should be afforded greater weight than the actual listing of SEQ ID No: 19 itself.

For all of the above reasons, the rejection of claim 22 based on “new matter” and the objection to the specification under 37 CFR 1.821(d) as set forth in paragraphs 4-7 should be withdrawn. However, should the Examiner believe that a further submission of the sequence listing is necessary, applicant would appreciate a telephone call to expedite satisfying the Examiner with regard to the sequence listing to overcome the rejection and any objection thereto based upon “new matter”.

The Examiner has indicated that claim 27, which was submitted as a new claim in the previous amendment filed in April 2010, is directed to an invention which is independent and/or distinct from the invention in claim 22 based solely on the fact that claim 27 is directed to a method for using the agent of claim 22.

Applicant acknowledges the withdrawal of claim 27 but requests reconsideration of this withdrawal since the Examiner has provided an argument in the office communication dated June 10, 2010, citing references relative to the patentability of

claim 27 under 35 USC 103 and accordingly applicant believes the basis for the restriction of claim 27 as being drawn to a non-elected invention is no longer relevant and should be withdrawn.

The rejection of claim 22 under 35 USC 102(b) as being anticipated by Kelly et al (J.Batho.1989) as is evidenced by Guignard (Feb. 1996) is respectfully traversed.

Applicant has amended claim 22 into a "product-by-process" claim which, for purposes of examination, is a product claim in Group IV and not an assay method for a calcium binding protein in Group V. However, claim 22, as now amended, is directed to a diagnostic agent for diagnosing inflammatory diseases in Group IV but is otherwise limited to the process consisting of forming a calcium binding protein assay reagent composed of a monoclonal antibody specific to a calcium-binding protein comprising an amino acid sequence shown in SEQ ID NO:19 or encoded by a nucleic acid sequence shown in SEQ ID NO:1 and using said calcium-binding protein assay reagent as the diagnostic agent to diagnose the presence of such diseases.

There is no teaching in Kelley of using a process consisting of forming a calcium-binding protein assay reagent composed of a monoclonal antibody as defined in claim 22 and using such calcium-binding protein assay reagent as the diagnostic agent to diagnose the presence of such diseases as called for in claim

22.

Accordingly, the rejection of claim 22 as now amended, is clearly not taught in Kelley as evidenced by Guignard et al and the rejection thereof under 35 USC 102(b) should be withdrawn.

The rejection of claim 22 under USC 103(a) as being unpatentable over Dell'Angelica (JBC, 269(46):28929-28936, 1994) as evidenced by the specification disclosure on page 40, lines 6-9 of Bost et al (Immunol. Invest. 1988) in view of Campbell (General Properties and applications of monoclonal antibodies, Elsevier Science Publishers 1984, §1.1) or USP 5,654,403 is respectfully traversed.

The Kelly reference carried out tissue staining of skin having inflammation using CF145 monoclonal antibody specific to calgranulin A, CF557 monoclonal antibody specific to calgranulin B, and MAC387 monoclonal antibody reactive both to calgranulin A and calgranulin B, and verified that calgranulin A and calgranulin B are stained in the skin tissue inflammation. However, they are not stained in skin tissue not having inflammation.

CAAF1 of the present invention does not have high homology with calgranulin A or calgranulin B, though it has a high homology with calgranulin C. In addition, according to the Kelly reference on page 18, MATERIALS AND METHODS, Control experiment, although bands of 10.5kd and 13.5kd correspond to calgranulin A and calgranulin B were detected in Western blot experiment using

an extract of skin tissue having inflammation, a band of 6kD corresponding to calgranulin C was not detected.

Therefore, the Kelly reference does not prove or suggest the existence of CAAF1 of the present invention nor is there any proof that calgranulin C was expressed in skin tissue.

Moreover, it cannot be predicted from the teaching in the Kelly reference that CAAF1 of SEQ ID NO:19 will function as an inflammatory marker.

The Examiner also alleges that according to the Dell 'Angelica reference, peptides T3 and T4 of calgranulin have 100% sequence homology with CAAF1 and based upon this, the Examiner further alleges that it should be easy to obtain an antibody specific to CAAF1.

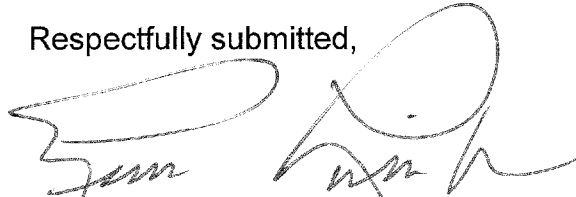
Even if it were possible to obtain, from the peptide teaching in Dell'Angelica, an antibody reactive with CAAF1, this does not prove or suggest that CAAF1 is a diagnostic agent or that it can be used as a diagnostic marker for diagnosing inflammations, cancers, dermatitis and blood diseases as specified in claim 22.

Claim 22 as now amended is limited to a diagnostic agent formed in accordance with a process consisting of forming a calcium binding protein assay reagent composed of a monoclonal antibody specific to a calcium-binding protein comprising an amino acid sequence shown in SEQ ID NO:19 or encoded by nucleic acid sequence shown in SEQ ID NO:1. This is clearly not suggested nor taught in Kelly or in Dell' Angelica for the reasons given above. Moreover, forming a calcium binding protein assay reagent as claimed does not suggest use of such calcium-binding protein assay reagent to diagnose the presence of the diseases specified in claim 22.

The arguments of the Examiner relative to a comparison of S100-like calcium-binding protein sequences which have sequence identities close to that of SEQ ID NO:19 is not applicable to claim 22 as currently amended since it is limited to a specific process consisting of a specific calcium binding protein assay reagent and not to other S100-like calcium-binding proteins and is also limited to a specific use which is clearly not taught or suggested in any of the references.

Reconsideration and allowance of claim 22 as amended and the withdrawal of claim 27 as a non-elected invention is respectively solicited.

Respectfully submitted,



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CERTIFICATE OF TRANSMISSION

I hereby certify that this Amendment is being deposited via EFS-Web addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on September 10, 2010.

